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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,253	08/27/2003	Zheng J. Li	PC11724D	7178

28523 7590 02/07/2006  
PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER

PESELEV, ELLI

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/650,253	LI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 125, 126 and 128-144 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 125, 126 and 128-144 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____.  | 6) <input type="checkbox"/> Other: _____.                                   |

Claims 125, 126 and 128-144 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement insofar as the claimed pharmaceutical dosage form reads on an aqueous solution the reasons set forth in the Office Action of September 12, 2005.

Applicant's arguments filed January 17, 2006 have been fully considered but they are not persuasive.

Applicant's argument with respect to solid dosage has been found persuasive. However, insofar as the instant claims read on an aqueous composition, there is a good reason to doubt that the claimed crystalline azithromycin can maintain its crystalline structure in water i.e. a person having ordinary skill in the art at the time the instant invention was made would have expected a crystalline compound dissolved in water to lose its crystalline structure.

Applicant's arguments with respect to other patents has not been found persuasive since each case is examined on its own merits.

Claims 125, 126 and 128-144 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bright (U.S. Patent No. 4,474,768) for the reasons set forth in the Office Action of September 12, 2005.

Applicant's arguments filed January 17, 2006 have been fully considered but they are not persuasive.

The declaration by Dr. Hangac has been considered but has not been found persuasive insofar as the claimed pharmaceutical dosage form reads on an aqueous solution since a person having ordinary skill in the art at the time the instant invention

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was made would not have expected to claimed crystalline azithromycin to maintain its crystalline structure. Once dissolved in water, a person having ordinary skill in the art at the time the instant invention was made would have expected the claimed compound and the compound disclosed by Bright to be the same.

Claims 125, 126 and 128-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al (U.S. Patent No. 6,365,574) in view of Curatolo et al (U.S. Patent No. 5,605,889).

Singer et al disclose a pharmaceutical composition comprising crystalline monohydrate hemi-ethanol (columns 3-4) but do not disclose said composition in dosage form. However, since a pharmaceutical dosage form of azithromycin was well known in the art at the time the instant invention was made as disclosed by Curatolo et al (column 2, lines 35-45), a person having ordinary skill in the art at the time the instant invention was made would have been motivated to prepare the composition disclosed by Singer et al in dosage form.

Applicant's arguments filed January 17, 2006 have been fully considered but they are not persuasive.

Applicant has submitted a declaration by Dr. Hancock showing that the Tensile Strength of the azithromycin monohydrate hemi-ethanol solvate is higher than that of 51% pure azithromycin hemi-ethanol solvate. The declaration has not been found persuasive because Singer et al disclose azithromycin monohydrate hemi-ethanol solvate having ethanol content of about 3% (see claim 1) i.e. the solvate disclosed by Singer et al reads on a substantially pure product. The data presented in the

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declaration fails to compare the claimed product with the product disclosed by Singer et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

  
ELLI PESELEV  
PRIMARY EXAMINER  
GROUP 1200